August 7, 2008

Sheila Westerveld
Regulatory Affairs Specialist
King Industries
P.O. Box 588
Science Road
Norwalk, CT 06852

Dear Ms. Westerveld:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for the Dinonylnaphthalene Category posted on the ChemRTK HPV Challenge Program Web site on January 19, 2005. I commend King Industries for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that King Industries advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. EPA has moved energetically from the HPV Challenge Program to the Chemical Assessment and Management Program, or ChAMP (www.epa.gov/champ), and is relying on Challenge chemical sponsors to provide, as expeditiously as possible, the data that are the key to this effort. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact me at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Mark W. Townsend, Chief
HPV Chemicals Branch

Enclosure

cc: R. Lee
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission:
Dinonylnaphthalene Category

Summary of EPA Comments

The sponsor, King Industries, submitted a test plan and robust summaries to EPA for the Dinonylnaphthalene Category, dated December 27, 2004. EPA posted the submission on the ChemRTK HPV Challenge Website on January 19, 2005. The proposed category consists of four substances: diisononylnaphthalene (CAS No. 63512-64-1), dinonylnaphthalene sulfonic acid (CAS No. 25322-17-2), dinonylnaphthalene sulfonic acid, calcium salt (CAS No. 57855-77-3) and dinonylnaphthalene sulfonic acid, barium salt (CAS No. 25619-56-1).

EPA has reviewed this submission and has reached the following conclusions:

1. Category Definition. (1) Although the definition is sufficient in this case for a screening-level evaluation, the submitter's CBI claim on more detailed structural information could hinder future more-detailed hazard/risk characterization. (2) The category name does not adequately describe the structure of most of the members.

2. Category Justification. The sharing of data between diisononylnaphthalene and the sulfonated category members is not justified.

3. Physicochemical Properties. Adequate data are available for these endpoints.

4. Environmental Fate. Adequate data are available for most endpoints. EPA agrees with the proposed biodegradation testing on dinonylnaphthalene sulfonic acid. In addition, EPA believes that biodegradation testing on diisononylnaphthalene is also needed

5. Health Effects. EPA agrees with the proposed testing for the human health endpoints using dinonylnaphthalene sulfonic acid, barium salt. However, the toxicity of the barium compound may not represent the toxicity of either the acid or the calcium salt. Thus the submitter needs to provide data for a second sulfonic acid derivative unless the submitter can provide further evidence to support the category and testing as proposed. Testing of the parent substance diisononylnaphthalene is also needed because it differs significantly from the other proposed category members (adequate support for closed system intermediate (CSI) status could reduce the testing needs for this substance).

6. Ecological Effects. EPA disagrees with the sponsor's proposed acute testing of dinonylnaphthalene sulfonic acid. EPA believes that, because of the very low estimated water solubility of all members of the category, acute or chronic toxicity is not expected at saturation in water and so no testing is needed.

EPA requests that the submitter advise the Agency within 90 days of any modifications to its submission.

EPA Comments on the Dinonylnaphthalene Category Challenge Submission

General

The Test Plan description of the category states that diisononylnaphthalene is a closed system intermediate but does not include a formal claim for CSI status with supporting information. The submitter may wish to clarify this statement. The guidance for testing a CSI can be found at: http://www.epa.gov/chemrtk/pubs/general/closed9.htm.

In a letter dated September 8, 2005 (http://www.epa.gov/chemrtk/pubs/summaries/dinapcat/c15766ct.pdf) EPA requested clarification as to whether the nonyl substituents are normal or branched. King Industries replied in a letter dated October 27, 2006 (http://www.epa.gov/chemrtk/pubs/summaries/dinapcat/c15766rr.pdf) but requested that the information about the nature of the alkyl substituent be treated as confidential business information (CBI). In order not to divulge CBI, EPA assumes in this review that the sponsored substance includes both branched and unbranched alkyl groups. In this specific case, the uncertainty does not significantly impact the evaluation. For example, whether or not the alkyl substituents are branched has little effect on the physical chemical properties because in both cases the calculated values are roughly similar and fall well outside the range where the properties need to be measured.

Category Definition

The dinonylnaphthalene category consists of the following four substances: diisononylnaphthalene (dinonylnaphthalene; CAS No. 63512-64-1), dinonylnaphthalene sulfonic acid (CAS No. 25322-17-2), dinonylnaphthalene sulfonic acid, barium salt (CAS No. 25619-56-1) and dinonylnaphthalene sulfonic acid, calcium salt (CAS No. 57855-77-3). The category definition is clear as to membership, but detailed structural information as to the nature of the alkyl chains is claimed as CBI. Information as to the distribution of possible isomers is also lacking.

As three of the four proposed category members bear the sulfonate function, it would be useful to reflect this feature in the category name.

Category Justification

Diisononylnaphthalene is manufactured by controlled alkylation of naphthalene with "nonene." It is the starting material for the other three category members; all are mixtures of isomers that the submitter considers confidential business information (CBI). The submitter groups the substances largely on the basis of similar physical chemical properties. However, there is an important structural difference, as three of the four category members have sulfonic acid functional groups. No information is provided on the structural diversity of the alkyl chains or the potential contribution of the metals to the toxicity of the two salts.

For human health, only acute data were submitted. These data do not illuminate the contribution of the sulfonic acid moiety to the toxicity of the category members (but see following paragraph for an apparent difference between the barium salt and other category members). The structure and physicochemical properties suggest that diisononylnaphthalene will behave differently from the acid and the salts with respect to bioavailability. EPA believes that the former substance needs to be tested separately from the other three.

EPA understands the proposal to test the dinonylnaphthalene sulfonic acid, barium salt since the available acute toxicity data show it to be the only category member with significant mortality (in two of three acute oral toxicity tests using the normal oral gavage method of test substance administration; the third study was an unusual single dose via feed study with no mortality). The other sulfonic acid category members had either minimal or no mortality following acute oral dosing in rats. Also, 8/10 rabbits died in the dermal acute toxicity study with the barium salt whereas there were no deaths in a similar study with the calcium salt. These data suggest that the barium metal may be bioavailable and toxic – which means the information may not be suitable to read across to the sulfonic acid or its calcium salt.

Thus, unless the sponsor can provide further evidence to support the category as proposed, in terms of human health effects the category members appear to fall into three subgroups, and testing is needed for three substances: (1) dinonylnaphthalene; (2) dinonylnaphthalene sulfonic acid OR dinonylnaphthalene sulfonic acid, calcium salt; and (3) dinonylnaphthalene sulfonic acid, barium salt.

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

Available data are adequate for the purposes of the HPV Challenge program. Calculated boiling points, vapor pressures, and water solubilities are well outside the ranges where measurements are necessary.

Melting point. The substances are all mixtures of isomers, are viscous liquids, and are unlikely to provide useful measured data.

Environmental Fate (photodegradation, stability in water, biodegradation and fugacity)

Adequate data are available for most endpoints for the purposes of the HPV Challenge program. EPA agrees with the proposed biodegradation testing on dinonylnaphthalene sulfonic acid. In addition, EPA believes that biodegradation testing on diisononylnaphthalene is also needed to adequately characterize these substances.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Adequate data were submitted for the acute toxicity endpoint for the purposes of the HPV Challenge program.

For the remaining endpoints, for reasons identified above, EPA believes testing is needed for diisononylnaphthalene; dinonylnaphthalene sulfonic acid OR dinonylnaphthalene sulfonic acid, calcium salt; and dinonylnaphthalene sulfonic acid, barium salt.

Genetic Toxicity. The submitter proposes *in vitro* testing of the barium salt for the gene mutations (OECD TG 471) and chromosomal aberrations (OECD TG 473) endpoints. EPA believes the same testing is also needed for two other substances as noted above.

Repeated-dose Toxicity. Testing is needed for three substances. The submitter proposes testing for this endpoint using the combined repeated-dose/reproductive/developmental toxicity screening study according to OECD TG 422 with dinonylnaphthalene sulfonic acid, barium salt. Should the submitter provide the information required to establish diisononylnaphthalene as a CSI, this testing requirement would be waived for that substance for the purposes of the HPV Challenge Program.

Reproductive/Developmental Toxicity. Testing is needed for three substances. The submitter states that testing for this endpoint with dinonylnaphthalene sulfonic acid, barium salt will depend on the outcome of the repeated-dose toxicity testing; however, the proposed combined testing following OECD TG 422 would also satisfy the reproductive and developmental toxicity endpoints for the barium salt. Should the submitter adequately support diisononylnaphthalene as a CSI, testing for reproductive toxicity for that substance would be waived for the purposes of the HPV Challenge Program. The submitter would still need to provide data for the developmental toxicity endpoint for diisononylnaphthalene, preferably according to OECD TG 421.

Ecological Effects (fish, invertebrates, and algae)

EPA disagrees with the proposed fish, daphnia and algal testing on dinonylnaphthalene sulfonic acid. EPA believes no testing is necessary because the estimated water solubility of the likely most water-soluble compound is only 0.028 ug/L and acute and chronic effects are not likely to occur.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.